UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PFIZER INC., PHARMACIA CORP., PHARMACIA & UPJOHN INC., PHARMACIA& UPJOHN COMPANY, G.D. SEARLE & CO, G.D. SEARLE LLC, SEARLE LLC (DELAWARE) and SEARLE LLC (NEVADA) Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	CIV. ACTION NO. 04-754 (JCL) **OPINION** Teva's In Limine Motion No. 4

LIFLAND, District Judge

This case arises out of Teva Pharmaceuticals U.S.A., Inc.'s ("Teva" or "Defendant") alleged infringement of U.S. Patent Nos. 5,466,823; 5,563,165; and 5,760,068 (the "patents-in-suit"), which are held by Pfizer, Inc., Pharmacia Corp., Pharmacia & Upjohn Inc., Pharmacia & Upjohn Company, G.D. Searle & Co., G.D. Searle LLC, Searle LLC (Delaware), and Searle LLC (Nevada) (collectively "Pfizer" or "Plaintiffs"). The patents-in-suit are directed toward celecoxib, the active ingredient in Celebrex, and a broad genus of compounds that includes celecoxib, pharmaceutical compositions including such compounds, and methods

of using such compounds.

Before the Court is Teva's in limine motion No. 4 to preclude evidence that Vioxx (Refocoxib) and Searle internal compounds are proper comparisons to Celebrex.

"One way for a patent [owner] to rebut a prima facie case of obviousness is to make a showing of 'unexpected results,' i.e. to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected." In re Soni, 54 F.3d 746, 750 (Fed. Cir. 1995). Pfizer has stated its intention to submit evidence demonstrating the unexpected superiority of Celebrex to another non-steroidal anti-inflammatory drug, Vioxx (and its active ingredient refocoxib), and to internal compounds created by G.D. Searle & Co. (the patentee), SC-58125 and SC-58236.

Neither party has explained the nature of the alleged unexpected results, but that is not the issue in this motion. The issue is whether Vioxx and the internal compounds are proper comparators for the purpose of an unexpected results inquiry. Specifically, Teva seeks to preclude the unexpected results evidence on the ground that these products are not prior art. Teva relies on the principle that "when unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art." In re Baxter

Travenol Labs, 952 F.2d 388, 392 (Fed. Cir. 1991) (emphasis added); see also, e.g., Novozymes A/S v. Genencor Int'l, Inc., 2006 U.S. Dist. LEXIS 60145, 62-63 (D. Del. 2006) ("Such results must be unexpected as compared to the closest prior art.").

I. The Searle Internal Compounds

With respect to the Searle internal compounds, Pfizer's argument that the comparison to Celebrex is appropriate is twofold. First, Pfizer argues that one of the compounds—SC-58125—is prior art. Second, Pfizer contends that it can rely on comparisons to both internal compounds (even if SC-58125 is not prior art) because a direct comparison with the prior art is unnecessary, and the compounds are "as close or closer in structure to celecoxib than any of the compounds which are argued by Teva to be the closest prior art." (Pfizer's Opposition to Defendant's Motion in Limine No. 4, at 4.)

A. Prior Art Status of SC-58125

Pfizer claims that SC-58125 constitutes prior art under 35 U.S.C. § 102(g).[1]

[1] Teva states in its brief that Pfizer claims SC-58125 is prior art because it falls within the broad genus of compounds contained in another patent. Teva correctly points out that disclosure of a genus in a prior art reference does not constitute a disclosure of all species within the genus. See Metabolite Labs, Inc. v. Laboratory Corp of America, 370 F.3d 1354, 1367 (Fed. Cir. 2004). However, Pfizer does not actually rely on this genus disclosure to establish that SC-58125 is prior art. Rather, Pfizer claims the compound constitutes prior art under § 102(g).

Section 102(g) defines prior art that may be used to demonstrate that an invention lacks novelty: "A person shall be entitled to a patent unless . . . before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." 35 U.S.C. § 102(g)(2). According to Pfizer, SC-58125 qualifies as prior art under this section because it was synthesized months before the invention of the patent in suit by Dr. Len F. Lee, who was not an inventor of the patents-in-suit, and who did not abandon, suppress, or conceal it. In support of the factual allegation that SC-58125 was synthesized in February 1993, Pfizer cites only the following sentence from the expert report of Dr. Galbraith: "Based on my review of lab notebooks of Monsanto and G.D. Searle & Co. . . . , I understand that in February 1993, Dr. Len F. Lee synthesized a compound called SC-58125." (Declaration of Daniel Reisner in Support of Pfizer's Opposition to Teva's Motions in Limine Nos. 1-7 (hereinafter, "Reisner Decl."), Ex. 14, ¶ 10.)

If this is the only evidence bearing on the issue of SC-58125's status as prior art, the Court would conclude that the compound meets the requirements to qualify as prior art under § 102(g). Accordingly, Teva's motion to preclude comparisons of Celebrex with SC-58125 would be denied. However, the Court will revisit this decision at trial if Pfizer is unable to establish all of the § 102(g)

requirements at trial—i.e. if Pfizer does not show that the compound was conceived and reduced to practice prior to the invention date of the patents-in-suit, and that the compound was not abandoned, suppressed, or concealed.

B. Indirect Comparison With SC-58236

Pfizer does not allege that SC-58236 is prior art. Pfizer argues that it is nevertheless appropriate to rely on comparisons between Celebrex and SC-58236 because direct comparison with the prior art is unnecessary, and the compound is structurally closer to celecoxib than any of the compounds which are argued by Teva to be the closest prior art.[2]

The predecessor to the Federal Circuit has held that a direct comparison with the closest prior art is unnecessary, and has sanctioned the use of "indirect comparisons." See In re Merchant, 575 F.2d 865, 869 n.8 (C.C.P.A. 1978) (sanctioning the use of indirect comparisons); In re Fouche, 439 F.2d 1237, 1241 (C.C.P.A. 1971). These indirect comparisons take the following form: (A), the claimed invention, is unexpectedly superior to (B), which is not prior art. (B) is superior to (C), which is prior art. In this situation, courts have found that evidence comparing (A) to (B) is permissible—even though (B) is not prior

[2] Notably, Teva does not mention SC-58236 in its motion papers. The Court will nevertheless address the compound because Pfizer intends to rely on I as a comparator.

art—because if (A) is better than (B), and (B) is better than (C), then (A) must be better than (C).

In In re Fouche, for example, the patent applicant relied on a comparison with an unsaturated compound even though the closest prior art was a saturated compound. The U.S. Patent Office Board of Appeals found this evidence insufficient because it did not compare the product with the closest prior art. The U.S. Court of Customs and Patents Appeals reversed. The Court explained that unsaturated compounds (which were not prior art) were superior to saturated ones (which were prior art). Because the applicant demonstrated that the claimed compound was superior to saturated ones, the Court held that his proffered evidence constituted a sufficient "indirect showing of unexpected superiority" over the prior art. 429 F.2d at 1241 ("Appellant's position involves a kind of indirect showing of unexpected superiority. . . . [H]is evidence showed that the claimed compound was more active than the best of the unsaturated derivatives; ergo, it is unexpectedly better than the saturated derivatives.").

Pfizer has not yet had occasion to demonstrate the existence of such a situation here—i.e., that SC-58236 is superior to the prior art. However, to the extent that Pfizer can make such a showing, the comparisons of Celebrex with SC-58236 will be permissible and relevant as an "indirect showing of unexpected

superiority" over the closest prior art.

The fact that SC-58236 is structurally closer to celecoxib than any of the compounds which are argued by Teva to be the closest prior art is irrelevant. In Ex parte Humber, 217 U.S.P.Q. (BNA) 265 (Bd. Pat. App. & Inf. 1981), the Board of Patent Appeals and Interferences did approve the use of comparison to non-prior art that was more closely related to the claimed compounds than the closest prior art:

> [A]ppellants may show improved results for their claimed compounds in comparison with compounds which, in fact, are even closer related than those of the prior art . . . . [T]he comparative showing vis-a-vis the other chlorinated compounds [non-prior art] which are more similar to those claimed than the non-chlorinated derivatives [the prior art] is viable probative evidence which palpably must be held as refuting the presumption of obviousness engendered by the art.

Id. However, this Court may not ignore the plain language of the numerous Federal Circuit cases requiring the comparison to be made—at least indirectly—to the prior art.

Accordingly, Teva's motion to preclude comparisons of Celebrex with SC-58236 will be denied at this time. However, the Court may revisit its ruling on this issue if Pfizer fails to establish the existence of an indirect comparison between Celebrex, SC-58236, and the prior art.

II. Vioxx

Pfizer appears to argue that it is appropriate to rely on a comparison between Celebrex and Vioxx because Vioxx is as close or closer to the so-called "Teva pharmacophore" than any other chemical compound.[3] Pfizer cites In re Fouche, discussed above, in support of its argument. As best as the Court can tell, Pfizer's argument is essentially as follows. The Teva pharmacophore constitutes prior art under Teva's obviousness theory. Since Vioxx is the closest compound to the hypothetical Teva pharmacophore, evidence that Celebrex is superior to Vioxx is permissible because it is an "indirect showing of unexpected superiority" over the prior art Teva pharmacophore. The Court finds this argument persuasive. Although this argument does not fit into the precise "if (A) is better than (B), and (B) is better than (C), then (A) must be better than (C)" formula discussed above, see supra Part I.B,[4] the Court finds that it does constitute an acceptable form of indirect comparison to the prior art. This comparison is particularly acceptable

[3] Teva's theory of obviousness (in somewhat simplified terms) seems to be that a hypothetical person with ordinary skill in the relevant art could construct a hypothetical pharmacophore (the "Teva pharmacophore") based on the Merck '995 patent and a European application, and then use the European application to select twelve compounds embraced by the pharmacophore, including celecoxib.

[4] The argument now is actually that if (A) is better than (B), and (B) is the closest thing to (C), then (A) must be better than (C).

here because the prior art reference is a hypothetical pharmacophore; because it does not actually exist, making a direct comparison is effectively impossible.

Importantly, this indirect comparison is viable only if Pfizer can establish that Vioxx is the functional equivalent of the Teva pharmacophore, and that the differences between the two compounds are irrelevant to the unexpected results at issue. Accordingly, Teva's motion to preclude comparisons of Celebrex with Vioxx will be denied.[5] However, the Court may revisit this decision if Pfizer is unable to establish at trial that Vioxx and the Teva pharmacophore are effectively equivalent.

/s/ John C. Lifland, U.S.D.J.

Dated: November 3, 2006

[5] The court notes, however, that for reasons discussed in the Court's Opinion in Teva's Motion in Limine 6—and unrelated to the disposition of this motion—Pfizer may not introduce evidence that Celebrex possesses unexpectedly superior cardiovascular properties as compared to Vioxx. (See Pfizer v. Teva, No. 04-754, Opinion on Teva's Motion in Limine No. 4.)